



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

FEE

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

~~CONTAINS CONFIDENTIAL BUSINESS INFORMATION~~

DP Barcode No.: D447834 File Symbol No.: 53883-UUU Decision No.: 536775
PC Code: 124002,128966,129032 Company Name: Control Solutions, Inc.
Food Use: No Action Code: R 314 Product Name: CSI 16-189 Concentrate

DATE OUT: August 23, 2018

SUBJECT: End-Use Product Chemistry Review
Product Name: CSI 16-189 Concentrate

FROM: Bruce F. Kitchens, Chemist
Product Chemistry Team
Chemistry, Inerts and Toxicology Assessment Branch/RD (7505P)

Bruce F. Kitchens
SPB
8/23/18

TO: RM #10, Richard Gebken/Matthew Sellner
Invertebrate and Vertebrate Branch 2
Registration Division (7505P)

INTRODUCTION:

The registrant, Control Solutions, Incorporated, is applying to register the proposed end-use product, CSI 16-189 Concentrate. The active ingredients in this product are (S)-Hydroprene, Novaluron and Pyriproxyfen at label nominal concentrations of 9.0, 2.60 and 2.60% a.i., respectively. This product is intended for use as an insect growth regulator. In support of this request, the registrant is submitting a proposed basic Confidential Statement of Formula (CSF) dated 08 Dec 2017; a draft label and product chemistry data contained in MRID#s 504684-01 and 504684-02. The Chemistry, Inerts and Toxicology Assessment Branch (CITAB) has been asked to review this submission.

SUMMARY OF FINDINGS:

1. Name of Active Ingredients: S-Hydroprene (9.00% a.i.)
Novaluron (2.60% a.i.)
Pyriproxyfen (2.60% a.i.)
2. Has the registrant claimed substantial similarity to a registered product?
[] Yes; [X] No; [] NA; if yes give the registration number of the cited product.
3. All of the source materials of the active ingredient are derived from registered sources- [X] Yes [] No
4. All inert ingredients have been screened by IIAB and are approved for the proposed labeled uses.

DP Barcode No.: D447834 File Symbol No.: 53883-UUU Decision No.: 536775
PC Code: 124002,128966,129032 Company Name: Control Solutions, Inc.
Food Use: No Action Code: R 314 Product Name: CSI 16-189 Concentrate

5. Confidential Statement of Formula:

☒ Basic - Dated: 08 Dec 2017 Resubmitted Dated:
☐ Alternate - Dated: N/A Resubmitted Dated:

Alternate CSF complies with 40 CFR 152.43
☐ Yes ☐ No ☒ NA

6. Product label

- a. Ingredient statement: Nominal concentration of AI listed on CSF concurs with product label (PR Notice 91-2).
☒ Yes, if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredient)?
☒ Yes; ☐ No; if not, explain below

Metallic equivalent: ☐ Yes ☒ NA
Soluble arsenic: ☐ Yes ☒ NA
Isomeric ratios: ☐ Yes ☒ NA
Acid Equivalent: ☐ Yes ☒ NA

- b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☐ Yes; ☐ No; ☒ NA
Methanol at > 4%: ☐ Yes; ☐ No; ☒ NA
Sodium nitrate/sodium nitrite ☐ Yes; ☐ No; ☒ NA

- c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for flammability, explosive potential or electric insulator breakdown?
☐ Yes ☒ No

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?
☐ Yes; ☐ No; ☒ NA; if not, explain below

- d. Label requires an additional Storage and Disposal statement: ☐ Yes ☒ No; if yes explain below

7. Group A: Product Chemistry Data

CITAB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		CITAB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		A	504684-01
830.1600	Description of materials used to produce the product		X		A	504684-01
830.1650	Description of formulation process		X		U	504684-01
830.1670	Discussion on the formation of impurities		X		A	504684-01
830.1700	Preliminary analysis			X	N/A	
830.1750	Certified limits (158.350)	Standard certified limits	X		A	504684-01
		Proposed Limits				
		Justification for wider limits				
830.1800	Enforcement analytical method			X	G	504684-01

A = Acceptable, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable; U = Upgradeable.

8. Group B:

Guideline No.	Study Title	Value or Qualitative Description	CITAB's Assessment of Data	MRID Nos.
830.6303	Physical State	This product is a pale amber liquid with a moderately sweet odor.	A	504684-02
830.6314	Oxidation/Reduction	Product is compatible when mixed with iron powder, ammonium phosphate and a hydrocarbon solvent. The product is not stable when mixed with water and potassium permanganate.	A	504684-02
830.6315	Flammability	231°F (setaflash)	A	504684-02
830.6316	Explosibility	Product not potentially explosive	N/A	
830.6317	Storage stability	Data not submitted	G	
830.6320	Corrosion Characteristics	Data not submitted	G	
830.7000	pH	4.6 (1% dispersion)	A	504684-02
830.7100	Viscosity	16.7 cP @ 24°C 10.6 cP @ 39°C	A	504684-02
830.7300	Density (units)	0.940 g/cm ³ @ 24°C 0.930 g/cm ³ @ 39°C	A	504684-02

A = Acceptable, N = Not Acceptable, G = Data Gap, W = Waiver request, NA = Not applicable, I = In progress; U = Upgradeable.

DP Barcode No.: D447834 File Symbol No.: 53883-UUU Decision No.: 536775
PC Code: 124002,128966,129032 Company Name: Control Solutions, Inc.
Food Use: No Action Code: R 314 Product Name: CSI 16-189 Concentrate

CONCLUSIONS:

CITAB has reviewed the product chemistry data submitted for the proposed end-use product and has concluded that:

A. Substantial similarity to the cited product (Reg. No.) from Product chemistry view point

- ☐ Similar
- ☐ Not similar, give reasons
- ☐ Identical
- ☐ Not identical
- ☒ Not applicable

B. Confidential Statement of formula

- 1. Basic CSF (dated 08 Dec 2017)
 - ☒ Acceptable (Subject to approval of data in 830.1650: Description of the Formulation Process)
 - ☐ Not Acceptable
 - ☐ Not Applicable

If not acceptable provide the reasons

- 2. Alternate CSF
 - ☐ Acceptable
 - ☐ Not Acceptable
 - ☒ Not Applicable

If not acceptable give reasons

C. Group A Product Chemistry Data

- ☐ Acceptable
- ☐ Not acceptable
- ☒ Acceptable with the exception of Guidelines: (830.1650 and 830.1800)
- ☐ Not required
- ☐ Data cited

The data requirement for the description of the formulation process requires updating. The description of the formulation process submitted provided no specific details of the process. Specific details of the data reporting required for the description of the formulation process are outlined in OCSPP Test Guidelines Series 830 Product Properties. This data is required prior to registration.

An analytical method with the accompanying method validation was not submitted. This data is required prior to registration.

DP Barcode No.: D447834 File Symbol No.: 53883-UUU Decision No.: 536775
PC Code: 124002,128966,129032 Company Name: Control Solutions, Inc.
Food Use: No Action Code: R 314 Product Name: CSI 16-189 Concentrate

D. Group B Product chemistry data

- ☐ Acceptable
- ☐ Not acceptable
- ☒ Acceptable with the exception of Guideline(s): (provide the guideline number & explain)
- ☐ Not required
- ☐ Data cited

Storage stability and corrosion characteristics data were not submitted. These data are required.

E. Product Label/Draft Label

Recommendations – Yes ☒; No ☐

If yes, give recommendations below:

Revise the physical and chemical hazards statement to read:

"Do not mix or allow contact with oxidizing agents with a final concentration of CSI 16-189 Concentrate in a ratio greater than 2:1. Hazardous chemical reaction may occur". In order to avoid incompatibility with water, the ratio of the product to water must not exceed the 2:1 ratio. This ratio was used in assessing the oxidation/reduction; chemical incompatibility of CSI 16-189 Concentrate.

Note: Please add additional remarks if necessary for each section

